Urgent Field Safety Notice

EASYGRIP FLO-41 Precision MIS Delivery System
FA-2021-033
Important Product Information

June 2021

Dear Healthcare Provider:

Problem Description	The EASYGRIP FLO-41 delivery system is intended for delivering compatible hemostatic agents to a bleeding site through a 5 mm or larger trocar.

Baxter has identified that the expiry date which is encoded into the 2D barcode located on the primary and secondary package labeling does not match the correct printed expiry date on the primary and secondary package labeling. The human-readable expiry dates printed on the primary and secondary package labeling are in the YYYY-MM-DD format, whereas the 2D barcode expiry date was encoded as the YY-DD-MM format.

Baxter is issuing this Important Product Information letter to communicate the discrepancy in the expiry date encoded into the 2D barcode and to inform customers that the correct expiration date is the human-readable date printed on the primary and secondary package labeling. The expiry date encoded into the 2D barcode presents itself after scanning the product.

Affected Product

Product Code	Product Description	Lot Number	Expiration Date MM/DD/YYYY
ADS201865	EASYGRIP FLO-41 Precision MIS Delivery System	0000345821	11/2/2021*
		0000350308	2/22/2024
		0000357425	3/8/2024
		0000366117	4/7/2024
		0000368579	4/13/2024
		0000379816	5/29/2024

* The shelf life for the product was extended after these lots were put on the market. Therefore, there is no risk with use of this product between the printed expiry date and the scanned expiry date.

Hazard Involved   An incorrect expiration date could lead to the use of expired product, which may subsequently lead to the hazardous situation of microbial contamination. This hazardous situation will not be realized as an analysis of the product lots in scope shows that they

are within shelf life, even accounting for the incorrectly labelled expiration dates. There have been no reports of serious injury associated with this issue.

Actions to be Taken by Customers

1. Healthcare providers may continue to safely use the EASYGRIP FLO-41 delivery system while following the human readable expiry date printed on the primary and secondary package labeling, which are also listed in the table above.

2. Complete the enclosed customer reply form and return it to Baxter by either faxing it or scanning and e-mailing it or sending it by post, even if you don't have any inventory. Returning the customer reply form promptly will confirm your receipt of this notification and prevent you from receiving repeat notices.

3. If you distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them.

For general questions regarding this communication, contact Baxter.

Further information and support

The local Ministry of Health (MOH) has been notified of this action.

We apologize for any inconvenience this may cause you and your staff.

Sincerely,

Baxter Healthcare Corporation

Baxter

CUSTOMER REPLY FORM

Product Name: EASYGRIP FLO-41 Precision MIS Delivery System
Product Code: ADS20186
Lot numbers: 0000345821, 0000350308, 0000357425, 0000366117, 0000368579, 0000379816

Please complete and return one copy of this form per facility as confirmation that you have received this notification.

Facility Name and Address:	
Reply Confirmation Completed By *(Please Print)*:	
Title *(Please print)*:	
Email and/or Telephone Number (including Area Code):	

Please check boxes as appropriate:

☐ We do not have any of the affected lots in our inventory.

☐ We do have the affected lots in our inventory and products have been quarantined.

Please list the quantity of the specific lot(s) to be returned below*:

Product Code	Lot number	Quantity in units to be returned

*You may attach an additional sheet if required.

Your signature below indicates that you have received the attached letter; performed the actions as outlined in the letter as needed; and disseminated this information to staff and other services or facilities as applicable.

Signature/Date: REQUIRED FIELD	_____